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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	<b>Application Number</b>	10/712,678	
	<b>Filing Date</b>	November 12, 2003	
	<b>First Named Inventor</b>	Gene Michal	
	<b>Group Art Unit</b>	3738	
	<b>Examiner Name</b>	Alvin J. Stewart	
<b>Total Number of Pages in This Submission</b>	268	<b>Attorney Docket Number</b>	50623.352

ENCLOSURES (check all that apply)		
<input checked="" type="checkbox"/> Deposit Account 07-1850 Authorization	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input checked="" type="checkbox"/> Postage Paid Return Postcard	<input type="checkbox"/> Drawing(s) In/Formal ___ Sheets with Submission of Drawings Transmittal	<input checked="" type="checkbox"/> Appeal Brief (265 pages)
<input type="checkbox"/> Response To Office Action	<input type="checkbox"/> Issue Fee Transmittal with PTO-85b (in duplicate)	<input type="checkbox"/> Notice of Appeal (in duplicate)
<input type="checkbox"/> Amendment Transmittal Letter (in duplicate)	<input type="checkbox"/> Request for Continued Examination (RCE) Transmittal (1 page) (in duplicate)	<input type="checkbox"/> Reasons For Request of Pre-Appeal Brief Review
<input type="checkbox"/> Statement of Common Ownership	<input checked="" type="checkbox"/> Fee Transmittal (1 page) (in duplicate)	<input type="checkbox"/> Request for Status of Application
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<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Zhaoyang Li, Ph.D., Reg. No. 46,872
Signature	
Date	July 10, 2007

CERTIFICATE OF MAILING			
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



Re Application Of:

Examiner: Alvin J. Stewart

Gene Michal

Art Unit: 3738

Serial No: 10/712,678

Filed: November 12, 2003

For: Ethylene-Carboxyl Copolymers As  
Drug Delivery Matrices

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**APPEAL BRIEF**

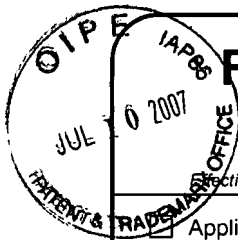
Dear Sir:

This Appeal Brief is submitted pursuant to receipt of an Advisory Action mailed on April 11, 2007, in which the examiner maintained his rejection of independent claims 44-54.

07/13/2007 ATRINH 00000001 071850 10712678  
01 FC:1402 500.00 DA

07/12/2007 ATRINH 00000049 071850 10712678  
01 FC:1402 500.00 DA

Void date: 07/12/2007 ATRINH  
07/12/2007 ATRINH 00000049 071850 10712678  
01 FC:1401 500.00 CR



# FEE TRANSMITTAL for FY 2007

Effective 10/01/2004. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 500.00

## Complete if Known

Application Number	10/712,678
Filing Date	November 12, 2003
First Named Inventor	Gene Michal
Examiner Name	Alvin J. Stewart
Art Unit	3738
Attorney Docket No.	50623.352

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money ☐ Other ☐ None  
Order
☒ Deposit Account:Deposit  
Account  
Number

07-1850

Deposit  
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Squire, Sanders &amp; Dempsey L.L.P.

The Director is authorized to: (check all that apply)

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## FEE CALCULATION

## 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	300	2001	150	Utility filing fee	
1002	200	2002	100	Design filing fee	
1003	200	2003	100	Plant filing fee	
1004	300	2004	150	Reissue filing fee	
1005	200	2005	100	Provisional filing fee	

SUBTOTAL (1)

(\$)

## 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims		Extra Claims		Fee from below		Fee Paid

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	50	2202	25	Claims in excess of 20
1201	200	2201	100	Independent claims in excess of 3
1203	360	2203	180	Multiple dependent claim, if not paid
1204	200	2204	100	** Reissue independent claims over original patent
1205	50	2205	25	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2)

(\$) 0

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1801	790	2801	395	Request for continued examination (RCE)	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	120	2251	60	Extension for reply within first month	
1252	450	2252	225	Extension for reply within second month	
1253	1,020	2253	510	Extension for reply within third month	
1254	1,590	2254	795	Extension for reply within fourth month	
1255	2,160	2255	1,080	Extension for reply within fifth month	
1401	500	2401	250	Notice of Appeal	
1402	500	2402	250	Filing a brief in support of an appeal	500
1403	1,000	2403	500	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	500	2452	250	Petition to revive - unavoidable	
1453	1,500	2453	750	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17 (q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1311	200	2311	100	Patent Examination Fee	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3)

(\$) 500.00

## SUBMITTED BY

## Complete (if applicable)

Name (Print/Type)	Zhaoyang Li, Ph.D.	Registration No. (Attorney/Agent)	46,872	Telephone	(415) 954-0200
Signature		Date	July 10, 2007		

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### REAL PARTY IN INTEREST

The real party in interest with regard to this appeal is Advanced Cardiovascular Systems Inc., a California corporation, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The original assignment to Advanced Cardiovascular system Inc. was recorded at Reel/Frame 011694/0183 on June 27, 2001. Effective February 13, 2007, Advanced Cardiovascular Systems Inc. changed its name to Abbott Cardiovascular Systems Inc.

### RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

### STATUS OF CLAIMS

Claims 44-54 are pending in the application.

Claims 44-54 are rejected and form the subject of this appeal.

Claims 37-49 were initially filed in this case as a divisional application of U.S. application No. 09/748,719, filed December 22, 2000, issued as U.S. Patent No. 6,824,559. Claims 37 and 44 are independent claims. Claims 38-43 depend from claim 37, and claim 45-49 depend from claim 44. In an office action mailed October 4, 2004 (**Evidence Appendix, "A"**), claims 37-49 were rejected as being obvious over U.S. Patent No. 6,379,379 to Wang ("Wang ") (**Evidence Appendix, "B"**) in view of U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni") (**Evidence Appendix, "C"**). Applicant responded on January 4, 2005, pointing out that Zaffaroni does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer (**Evidence Appendix, "D"**). Applicants argued that claims 37-49 are non-obvious over Wang in view of Zaffaroni.

On March 22, 2005, the examiner issued another office action (**Evidence Appendix, "E"**), in which the examiner allowed claims 44-49, but again rejected claims 37-43 as being anticipated by U.S. Patent No. 6,738,661 to Nyhart, Jr. under 35 U.S.C. 102(e) ("Nyhart") (**Evidence Appendix, "F"**). The examiner argued that Medtronic describes a polymer coating composition having a heparin adduct and further comprising poly(ethylene glycol) chains. Applicants responded on June 29, 2005

(**Evidence Appendix, "G"**), pointing out that Nyart does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer. Applicants argued that Nyart does not anticipate claims 37-43. On June 29, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on June 22, 2005 fails to provide a list of claims and the claims were not presented in ascending numerical order (**Evidence Appendix, "H"**). Applicants addressed the non-compliance issues by a communication mailed on July 7, 2005 (**Evidence Appendix, "I"**).

On September 29, 2005, the examiner mailed an office action (**Evidence Appendix, "J"**), withdrawing the rejections of claims 37-43 over Nyart, but rejecting these claims as being anticipated by U.S. Patent No. 5,401,512 to Rhodes ("Rhodes") (**Evidence Appendix, "K"**) under 35 U.S.C. 102(b). Applicants responded on November 30, 2005, amending claim 37 to additionally recite "wherein the copolymer is a coating on an implantable substrate" (**Evidence Appendix, "L"**). Applicants pointed out that Rhodes describes "an orally administrable formulation for selectively administering the drug to the large intestine" but fails to teach or suggest all the limitations of Claim 37 and that claims 37-43 are thus allowable over Rhodes. On December 14, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on November 30, 2005 fails to provide to a proper status identifier to the claims (**Evidence Appendix, "M"**). Applicants addressed the non-compliance issues by a communication mailed on January 6, 2006, in which Applicants also canceled claim 43 and added new claims 50-55 (**Evidence Appendix, "N"**).

On March 22, 2006, the examiner mailed a final office action (**Evidence Appendix, "O"**), allowing claims 44-54, and rejecting claims 37-42 and 55 as being anticipated by Rhodes under 35 U.S.C. 102(b). The examiner alleged that the limitation "wherein the copolymer is a coating on an implantable substrate" is functional and thus would not add patentability weight to the claims. Applicants responded on May 8, 2006, amending the claims to recite "a drug delivery coating on an implantable medical device" instead of "a drug delivery matrix" (**Evidence Appendix, "P"**). Applicants pointed out that Rhodes fails to provide a drug delivery coating. On May 25, 2006, the examiner mailed an advisory action (**Evidence Appendix, "Q"**), refusing to enter the

amended claims. On June 2, 2006, Applicants filed a supplemental response to final office action, canceling all the rejected claims, claims 37-42 and 55 (**Evidence Appendix, "R"**).

On August 24, 2006, the examiner mailed an office action (**Evidence Appendix, "S"**), rejecting claims 50-52 as indefinite, rejecting claims 44-46 and 53-54 as being anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b), and rejecting claims 47, 48 and 50-52 over Wang II in view of U.S. Patent No. 6,087,412 to Chabreck et al. ("Chabreck") (**Evidence Appendix, "U"**) and claim 49 over Wang II in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) as being obvious under 35 U.S.C. 103(a). Applicants responded on November 7, 2006, pointing out that Wang II describe a composition that includes (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid but not a copolymer of an ethylene comonomer with a carboxylic acid comonomer (**Evidence Appendix, "W"**). Applicants further pointed that both Chabreck and Kliment fail to provide a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants argued that claims 44-54 are allowable.

On February 12, 2007, the examiner mailed a final office action (**Evidence Appendix, "X"**), maintaining the rejections of claims as set forth in the Office Action mailed on August 24, 2006. The examiner further rejected claims 44-54 as failing to comply with the written description requirement. Applicants responded on March 21, 2007, in which Applicants amended the specification to make the claims to comply with the written description requirement but did not amend the claims. Applicants again pointed out that none of Wang II Chabreck and Kliment describe or teach a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants again argued that claims 44-54 are allowable.

On April 11, 2007, the examiner mailed an advisory action (**Evidence Appendix, "Y"**), maintaining the rejections of claims as set forth in the Final Office Action mailed on February 21, 2007.

Amendments in the response to Final Office Action filed on March 21, 2007 have been entered. Thus, claims 44-54 as pending on March 21, 2007, are the subject of this appeal.

### STATUS OF AMENDMENTS

As indicated above, amendments in the Response to Final Office Action filed January 8, 2007 and prior amendments have been entered and are before the Board.

### SUMMARY OF THE CLAIMED SUBJECT MATTER

The claimed invention relates to a method of coating an implantable medical device. Claim 44 is the sole independent claim, which succinctly set forth the invention:

44. A method of coating an implantable medical device, comprising:  
adding a copolymer of an ethylene comonomer with a carboxylic acid  
comonomer to a solvent system to form a composition;  
applying the composition to an implantable medical device; and  
allowing the solvent system to evaporate.

Support for claim 44 is found at least at page 3, line 21 to page 4, line 4; and page 17, line 21 to page 18, line 7 (Example 9) of the specification.

Claims dependent from claims 44 further define the scope of the invention in different aspects. The complete claim set as currently entered is provided in the **Claims Appendix**.

### GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented in this appeal are:

- (1) Whether claims 44-46 and 53-54 are anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b);
- (2) whether claims 47, 48 and 50-52 are obvious over Wang II in view of U.S. Patent No. 6,087,412 to Chabreck et al. ("Chabreck") (**Evidence Appendix, "U"**) under 35 U.S.C. 103(a); and
- (3) whether claim 49 is obvious over Wang II in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) under 35 U.S.C. 103(a).

## ARGUMENT

### (1). Claims 44-46 and 53-54 are allowable over U.S. Patent No. 5,631,328 to Wang II under 35 U.S.C. 102(b)

#### A. The Law

Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). When the claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. Thus, the invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim. See Karsten Mfg. Corp. v. Cleveland Gulf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); Akzo N.V. v. International Trade Commission, 808 F.2d 1471, 1480, 1 USPQ2d 1241, 1245-46 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987); In re Arkley, 455 F.2d 586, 587-88, 172 USPQ 524, 526 (CCPA 1972).

#### B. The Analysis

The examiner's rejection does not follow the guidelines provided by the Courts. Claim 44 defines a method of coating an implantable medical device. The method includes the acts of (1) adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition, (2) applying the composition to an implantable medical device, and (3) allowing the solvent system to evaporate.

In contrast, Wang II describes forming a composition of ionomers that can form a film (col. 6, lines 17-63). The composition can be formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid (see col. 2, lines 55 and 56), and (c) a metal salt of acrylic or methacrylic acid (col. 2, lines 55-59; col. 4, line 59 through col. 5, line 63).



Therefore, Wang II does not describe forming a coating including a copolymer of an ethylene comonomer with a carboxylic acid comonomer. A person of ordinary skill in the art can readily appreciate that **esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid.**

In the Office Action mailed on February 12, 2007, the examiner states that Wang II reads on the claims because the two compounds mentioned in the claim are part of a copolymer (page 3, middle paragraph). Applicant respectfully fails to see the relevance of this statement. Applicant can certainly see that Wang II describes a copolymer. However, **the copolymer described by Wang II is entirely different from the copolymer defined by claim 44** (see the discussion above).

In sum, claim 44 is not anticipated by Wang II under 35 U.S.C. §102(b). Claims 45, 46, 53 and 54 depend from claim 44 and are not anticipated by Wang II under 35 U.S.C. §102(b) for at least the same reason.

**(2) Claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabreck under 35 U.S.C. 103(a)**

**A. The Law**

Claims are non-obvious if the claimed subject matter is more than a predictable use of prior art elements according to their established functions (see, *KSR International Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_, Slip Opinion No. 04-1350, page 13 (2007)).

Claims 47, 48 and 50-52 all depend from claim 44 and therefore all recite a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Wang II fails to provide for this copolymer (see the discussion above). Chabreck describes a macromer that include a segmented copolymer, **which is an amide** (col. 1, line 20 through col. 2, line 23). Chabreck describes toluene as a solvent but does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Chabreck together do not teach the element "a copolymer of an ethylene comonomer with a carboxylic acid comonomer."

As mentioned previously, esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid. In addition, esters of a carboxylic acid and metal salts of a carboxylic acid have totally different physical and mechanical properties than the carboxylic acid. For example, as

an ordinary artisan would recognize, an ester of a carboxylic acid is more hydrophobic than the carboxylic acid. Conversely, a metal salt of the carboxylic acid is more hydrophilic than the carboxylic acid. A film formed of an ester of a carboxylic acid or a metal salt of a carboxylic acid would have totally different physical, mechanical, or drug release properties than a film formed of a carboxylic acid. A key aspect of the Wang II reference is to use a combination of an ester and metal salt of a carboxylic acid monomers for forming a film which has low haze (col. 1, lines 13-19), which attests to the different film properties different monomers in a polymer of the film can impart to the film. As such, to a person of ordinary skill in the art, a copolymer of an ethylene comonomer with a carboxylic acid comonomer as defined by any of claims 47, 48 and 50-52 is not a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid as described by Wang II.

Further, each of claims 47, and 50-52 includes limitations that carry additional patentability weight. Claim 47 further recites adding a therapeutic agent to the solvent system, and claims 50-55 require the carboxylic acid co-monomer content in the copolymer to be no less than 5% by weight and/or no more than 50% by weight.

In sum, claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabreck under 35 U.S.C. 103(a)

**(3) Claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. 103(a)**

Claim 49 depends from claim 48, which recites a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Claim 49 further requires the solvent system to further comprise a chlorinated solvent and a lower alcohol.

Wang II is discussed above. Kliment describes a copolymer that can be dissolved in a chlorinated solvent. However, Kliment does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Kliment together do not teach the element, a copolymer of an ethylene comonomer with a carboxylic acid comonomer. As the above discussion shows, this copolymer is NOT a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of

acrylic or methacrylic acid as described by Wang II. Accordingly, claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. §103(a).

### CONCLUSION

The examiner has failed, as a matter of law, to set forth a case of anticipation of claims 44-46 and 53-54 by Wang II under 35 U.S.C. 102(b).

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 47, 48 and 50-52 under 35 U.S.C. 103(a) over Wang II in view of Chabreck.

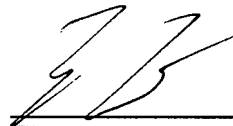
The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 49 under 35 U.S.C. 103(a) over Wang II in view of Kliment.

Appellants therefore respectfully request that the Board reverse the rejections and order the application to be passed to issue.

Date: July 10, 2007

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Respectfully submitted,



Zhaoyang Li, Ph.D., Esq.  
Reg. No. 46,872

# CLAIMS APPENDIX

**WHAT IS CLAIMED:**

1-43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid comonomer is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no less than 5% by weight.

51. (Previously presented) The method of claim 50, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

# EVIDENCE APPENDIX



Attached hereto are the following:

- (A) Office action mailed October 4, 2004;
- (B) U.S. Patent No. 6,379,379 to Wang ("Wang ");
- (C) U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni");
- (D) Response to Office Action filed on January 4, 2005;
- (E) Office Action mailed on March 22, 2005;
- (F) U.S. Patent No. 6,738,661 to Nyhart, Jr. ("Nyhart");
- (G) Response to Office Action mailed on June 29, 2005;
- (H) Notice of non-compliant amendment mailed on June 22, 2005;
- (I) Response to Notice of non-compliant amendment mailed on July 7, 2005;
- (J) Office Action mailed on September 29, 2005;
- (K) U.S. Patent No. 5,401,512 to Rhodes ("Rhodes");
- (L) Response to Office Action mailed on November 30, 2005;
- (M) Notice of non-compliant amendment mailed on December 14, 2005;
- (N) Response to Notice of non-compliant amendment mailed on January 6, 2006;
- (O) Final Office Action mailed on March 22, 2006;
- (P) Response to Final Office Action mailed on May 8, 2006;
- (Q) Advisory Action mailed on May 25, 2006;
- (R) Supplemental Response to Final Office Action mailed on June 2, 2006;
- (S) Office Action mailed on August 24, 2006;
- (T) U.S. Patent No. 5,631,328 to Wang et al. ("Wang II");
- (U) U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek");
- (V) U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment");
- (W) Response to Office Action mailed on November 7, 2006;
- (X) Final Office Action mailed on February 12, 2007; and
- (Y) Advisory Action mailed on April 11, 2007.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590

10/04/2004

Cameron K. Kerrigan  
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Suite 300  
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San Francisco, CA 94111

EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED *Response*  
*due 01/04/05*  
OCT 07 2004  
BY *ckpr* CALENDARED  
ATTORNEY  
SQUIRE, SANDERS & DEMPSEY

**Office Action: Summary**

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Hieu Phan

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/19/2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Specification***

1. The abstract of the disclosure is objected to because legal phraseology have been used. The legal terms "comprises" were used in the abstract and correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (U.S. Patent 6,379,379) in view of Zaffaroni et al. (U.S. Patent 4,142,526).

Wang disclose a stent (10) made can be metal stent or polymeric stent having a coating contain drugs such as antithrombin or antiplatelet compounds as is claimed (Entire document but especially the following passages: Abstract, Figures 1-12, column 2 lines 26-67, column 3 lines 1-8 and 59-67, column 4 lines 1-34, column 5 lines 19-67 and column 6 lines 1-30). But Wang fails to disclose the carboxylic acid co-monomer content between 5-50 wt%.

Zaffaroni et al. teach an implant having a drug release coating with the carboxylic acid co-monomer content between 5-50 wt%. The advantage of having the carboxylic acid co-monomer content between 5-50 wt% is the release rate of the drugs can be vary by increase the co-monomer content.

Art Unit: 3738

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Zaffaroni et al. to modify the apparatus Wang to have the carboxylic acid co-monomer content between 5-50 wt%. The motivation for incorporating the feature of Zaffaroni et al. into the apparatus of Wang the release rate of the drugs can be vary by increase the co-monomer content.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan



<b>FORM PTO-1449 (Modified)</b> Approved for use through 3/31/2002 <b>INFORMATION DISCLOSURE CITATION</b> in an Application (Use several sheets if necessary)		US DEPARTMENT OF COMMERCE US Patent and Trademark Office		Docket No. <b>50623.352</b>	Application No. <b>10/712,678</b>
				Applicant <b>Gene Michal</b>	
				Filing Date <b>November 12, 2003</b>	Group Art Unit <b>1615</b>

### U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
<input checked="" type="checkbox"/>	A1	4,142,526	3/6/79	Zaffaroni et al.	424	424	3/9/77
<input type="checkbox"/>	A2	4,329,383	5/11/82	Joh	428	36	7/21/80
<input type="checkbox"/>	A3	4,733,665	3/29/88	Palmaz	128	343	11/7/85
<input type="checkbox"/>	A4	4,800,882	1/31/89	Gianturco	128	343	3/13/87
<input type="checkbox"/>	A5	4,882,168	11/21/89	Casey et al.	424	468	9/5/86
<input type="checkbox"/>	A6	4,886,062	12/12/89	Wiktor	128	343	10/19/87
<input type="checkbox"/>	A7	4,941,870	7/17/90	Okada et al.	600	36	12/30/88
<input type="checkbox"/>	A8	4,977,901	12/18/90	Ofstead	128	772	4/6/90
<input type="checkbox"/>	A9	5,112,457	5/12/92	Marchant	204	165	7/23/90
<input type="checkbox"/>	A10	5,165,919	11/24/92	Sasaki et al.	424	488	9/26/90
<input type="checkbox"/>	A11	5,272,012	12/21/93	Opolski	428	423.1	1/29/92
<input type="checkbox"/>	A12	5,292,516	3/8/94	Viegas et al.	424	423	11/8/91
<input type="checkbox"/>	A13	5,298,260	3/29/94	Viegas et al.	424	486	6/9/92
<input type="checkbox"/>	A14	5,300,295	4/5/94	Viegas et al.	424	427	9/13/91
<input type="checkbox"/>	A15	5,306,501	4/26/94	Viegas et al.	424	423	11/8/91
<input type="checkbox"/>	A16	5,328,471	7/12/94	Slepian	604	101	8/4/93
<input type="checkbox"/>	A17	5,330,768	7/19/94	Park et al.	424	501	7/5/91
<input type="checkbox"/>	A18	5,380,299	1/10/95	Feamot et al.	604	265	8/30/93
<input type="checkbox"/>	A19	5,417,981	5/23/95	Endo et al.	424	486	4/28/93
<input type="checkbox"/>	A20	5,447,724	9/5/95	Helmus et al.	424	426	11/15/93
<input type="checkbox"/>	A21	5,455,040	10/3/95	Marchant	424	426	11/19/92
<input type="checkbox"/>	A22	5,462,990	10/31/95	Hubbell et al.	525	54.1	10/5/93
<input type="checkbox"/>	A23	5,464,650	11/7/95	Berg et al.	427	2.30	4/26/93
<input type="checkbox"/>	A24	5,569,463	10/29/96	Helmus et al.	424	426	6/7/95
<input type="checkbox"/>	A25	5,578,073	11/26/96	Haimovich et al.	623	1	9/16/94
<input type="checkbox"/>	A26	5,605,696	2/25/97	Eury et al.	424	423	3/30/95

22	A27	5,609,629	3/11/97	Fearnott et al.	623	1	6/7/95
	A28	5,624,411	4/29/97	Tuch	604	265	6/7/95
	A29	5,628,730	5/13/97	Shapland et al.	604	21	7/18/94
	A30	5,649,977	7/22/97	Campbell	623	1	9/22/94
	A31	5,658,995	8/19/97	Kohn et al.	525	432	11/27/95
	A32	5,667,767	9/16/97	Greff et al.	424	9.411	7/27/95
	A33	5,670,558	9/23/97	Onishi et al.	523	112	7/6/95
	A34	5,679,400	10/21/97	Tuch	427	2.14	6/7/95
	A35	5,700,286	12/23/97	Tartaglia et al.	623	1	8/22/96
	A36	5,702,754	12/30/97	Zhong	427	2.12	2/22/95
	A37	5,716,981	2/10/98	Hunter et al.	514	449	6/7/95
	A38	5,735,897	4/7/98	Burge	623	12	1/2/97
	A39	5,746,998	5/5/98	Torchilin et al.	424	9.4	8/8/96
	A40	5,776,184	7/7/98	Tuch	623	1	10/9/96
	A41	5,788,979	8/4/98	Alt et al.	424	426	2/10/97
	A42	5,800,392	9/1/98	Racchini	604	96	5/8/96
	A43	5,820,917	10/13/98	Tuch	427	2.1	6/7/95
	A44	5,824,048	10/20/98	Tuch	623	1	10/9/96
	A45	5,824,049	10/20/98	Ragheb et al.	623	1	10/31/96
	A46	5,830,178	11/3/98	Jones et al.	604	49	10/11/96
	A47	5,837,008	11/17/98	Berg et al.	623	1	4/27/95
	A48	5,837,313	11/17/98	Ding et al.	427	2.21	6/13/96
	A49	5,851,508	12/22/98	Greff et al.	424	9.411	2/14/97
	A50	5,858,746	1/12/99	Hubbell et al.	435	177	1/25/95
	A51	5,865,814	2/2/99	Tuch	604	265	8/6/97
	A52	5,869,127	2/9/99	Zhong	427	2.12	6/18/97
	A53	5,873,904	2/23/99	Ragheb et al.	623	1	2/24/97
	A54	5,876,433	3/2/99	Lunn	623	1	5/29/96
	A55	5,877,224	3/2/99	Brocchini et al.	514	772.2	7/28/95
	A56	5,925,720	7/20/99	Kataoka et al.	525	523	12/18/97
	A57	5,955,509	9/21/99	Webber et al.	514	772.7	4/23/97
	A58	5,971,954	10/26/99	Conway et al.	604	96	1/29/97

A59	5,980,928	11/9/99	Terry	424	427	7/29/97
A60	5,980,972	11/9/99	Ding	427	2.24	9/22/97
A61	5,997,517	12/7/99	Whitbourne	604	265	1/27/97
A62	6,010,530	1/4/00	Goicoechea	623	1	2/18/98
A63	6,015,541	1/18/00	Greff et al.	424	1.25	11/3/97
A64	6,033,582	3/7/00	Lee et al.	216	37	1/16/98
A65	6,042,875	3/28/00	Ding et al.	427	2.24	3/2/99
A66	6,051,648	4/18/00	Rhee et al.	525	54.1	1/13/99
A67	6,051,576	4/18/00	Ashton et al.	514	255	1/29/97
A68	6,056,993	5/2/00	Leidner et al.	427	2.25	4/17/98
A69	6,060,451	5/9/00	DiMaio et al.	514	13	3/20/95
A70	6,060,518	5/9/00	Kabanov et al.	514	781	8/16/96
A71	6,080,488	6/27/00	Hostettler et al.	428	423.3	3/24/98
A72	6,096,070	8/1/00	Ragheb et al.	623	1	5/16/96
A73	6,099,562	8/8/00	Ding et al.	623	1.46	12/22/97
A74	6,110,188	8/29/00	Narciso, Jr.	606	153	3/9/98
A75	6,110,483	8/29/00	Whitbourne et al.	424	423	6/23/97
A76	6,113,629	9/5/00	Ken	623	1.1	5/1/98
A77	6,120,536	9/19/00	Ding et al.	623	1.43	6/13/96
A78	6,120,904	9/19/00	Hostettler et al.	428	423.3	5/24/99
A79	6,121,027	9/19/00	Clapper et al.	435	180	8/15/97
A80	6,129,761	10/10/00	Hubbell	623	11	6/7/95
A81	6,153,252	11/28/00	Hossainy et al.	427	2.3	4/19/99
A82	6,165,212	12/26/00	Dereume et al.	623	1.13	6/28/99
A83	6,197,013	3/6/01	Reed et al.	604	509	11/6/96
A84	6,200,337	3/13/01	Moriuchi et al.	623	1.16	11/18/98
A85	6,203,551	3/20/01	Wu	606	108	10/4/99
A86	6,206,916	3/27/01	Furst	623	1.46	7/29/99
A87	6,231,600	5/15/01	Zhong	623	1.42	5/26/99
A88	6,240,616	6/5/01	Yan	29	527.2	4/15/97
A89	6,245,753	6/12/01	Byun et al.	514	56	4/27/99



Q	A90	6,251,136	6/26/01	Guruwaiya et al.	623	1.46	12/8/99
	A91	6,254,632	7/3/01	Wu et al.	623	1.15	9/28/00
	A92	6,258,121	7/10/01	Yang et al.	623	1.46	7/2/99
	A93	6,283,947	9/4/01	Mirzaee	604	264	7/13/99
	A94	6,283,949	9/4/01	Roorda	604	288.02	12/27/99
	A95	6,284,305	9/4/01	Ding et al.	427	2.28	5/18/00
	A96	6,287,628	9/11/01	Hossainy et al.	427	2.3	9/3/99
	A97	6,299,604	10/9/01	Ragheb et al.	604	265	8/20/99
	A98	6,306,176	10/23/01	Whitbourne	623	23.59	9/21/99
	A99	6,331,313	12/18/01	Wong et al.	424	427	10/22/99
	A100	6,335,029	1/1/02	Kamath et al.	424	423	12/3/98
	A101	6,346,110	2/12/02	Wu	606	108	1/3/01
	A102	6,358,556	3/19/02	Ding et al.	427	2.24	1/23/98
	A103	6,379,381	4/30/02	Hossainy et al.	623	1.42	9/3/99
	A104	6,379,379	4/30/02	Wang	623	1.15	8/13/99
	A105	6,395,326	5/28/02	Castro et al.	427	2.24	5/31/00
	A106	6,419,692	7/16/02	Yang et al.	623	1.15	2/3/99
	A107	6,451,373	9/17/02	Hossainy et al.	427	2.25	8/4/00
	A108	6,494,862	12/17/02	Ray et al.	604	96.01	12/30/99
	A109	6,503,556	1/7/03	Harish et al.	427	2.24	12/28/00
	A110	6,503,954	1/7/03	Bhat et al.	514	772.2	7/21/00
	A111	6,506,437	1/14/03	Harish et al.	427	2.25	10/17/00
	A112	6,527,801	3/4/03	Dutta	623	1.46	4/13/00
	A113	6,527,863	3/4/03	Pacetti et al.	118	500	6/29/01
	A114	6,540,776	4/1/03	Sanders Millare et al.	623	1.15	12/28/00
	A115	6,544,223	4/8/03	Kokish	604	103.01	1/5/01
	A116	6,544,543	4/8/03	Mandrusov et al.	424	422	12/27/00
	A117	6,544,582	4/8/03	Yoe	427	2.24	1/5/01
	A118	6,555,157	4/29/03	Hossainy	427	2.24	7/25/00

	A119	6,558,733	5/6/03	Hossainy et al.	427	2.24	10/26/00
	A120	6,565,659	5/20/03	Pacetti et al.	118	500	6/28/01
	A121	6,572,644	6/3/03	Moein	623	1.11	6/27/01
	A122	6,585,765	7/1/03	Hossainy et al.	623	1.45	6/29/00
	A123	6,585,926	7/1/03	Mirzaee	264	400	8/31/00
	A124	6,605,154	8/12/03	Villareal	118	500	5/31/01

### U.S. PATENT APPLICATION PUBLICATION DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Name	Class	Subclass	Filing Date If Appropriate
	A125	2001/0018469	8/30/01	Chen et al.	523	121	12/28/00
	A126	2001/0037145	11/1/01	Guruwaiya et al.	623	1.15	6/21/01
	A127	2002/0077693	6/20/02	Barclay et al.	623	1.13	12/19/00
	A128	2002/0091433	7/11/02	Ding et al.	623	1.2	12/17/01
	A129	2002/0155212	10/24/02	Hossainy	427	2.25	4/24/01
	A130	2003/0065377	4/3/03	Davila et al.	623	1.13	4/30/02
	A131	2003/0099712	5/29/03	Jayaraman	424	486	11/26/01

### FOREIGN PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Publication	Country	Class	Subclass	Translation	
							Yes	No
	B1	EP 0 301 856	2/1/89	European				
	B2	EP 0 514 406	11/25/92	European				
	B3	EP 0 604 022	6/29/94	European				
	B4	EP 0 623 354	11/9/94	European				
	B5	EP 0 665 023	8/2/95	European				
	B6	EP 0 701 802	3/20/96	European				
	B7	EP 0 716 836	6/19/96	European				
	B8	EP 0 809 999	12/3/97	European				
	B9	EP 0 832 655	4/1/98	European				
	B10	EP 0 850 651	7/1/98	European				
	B11	EP 0 879 595	11/25/98	European				
	B12	EP 0 910 584	4/28/99	European				
	B13	EP 0 923 953	6/23/99	European				
	B14	EP 0 953 320	11/3/99	European				
	B15	EP 0 970 711	1/12/00	European				

<input checked="" type="checkbox"/>	B16	EP 0 982 041	3/1/00	European				
<input checked="" type="checkbox"/>	B17	EP 1 273 314	1/8/03	European				
<input checked="" type="checkbox"/>	B18	2001-190687	7/17/01	Japan (Abstract)			X	
<input checked="" type="checkbox"/>	B19	WO 91/12846	9/5/91	PCT				
	B20	WO 95/10989	4/27/95	PCT				
	B21	WO 96/40174	12/19/96	PCT				
	B22	WO 97/10011	3/20/97	PCT				
	B23	WO 97/45105	12/4/97	PCT				
	B24	WO 97/46590	12/11/97	PCT				
	B25	WO 98/17331	4/30/98	PCT				
	B26	WO 98/36784	8/27/98	PCT				
	B27	WO 99/01118	1/14/99	PCT				
	B28	WO 99/38546	8/5/99	PCT				
	B29	WO 99/63981	12/16/99	PCT				
	B30	WO 00/02599	1/20/00	PCT				
	B31	WO 00/12147	3/9/00	PCT				
	B32	WO 00/18446	4/6/00	PCT				
	B33	WO 00/64506	11/2/00	PCT				
	B34	WO 01/01890	1/11/01	PCT				
	B35	WO 01/15751	3/8/01	PCT				
	B36	WO 01/17577	3/15/01	PCT				
	B37	WO 01/45763	6/28/01	PCT				
	B38	WO 01/49338	7/12/01	PCT				
	B39	WO 01/74414	10/11/01	PCT				
	B40	WO 02/03890	1/17/02	PCT				
	B41	WO 02/026162	4/4/02	PCT				
	B42	WO 02/34311	5/2/02	PCT				
	B43	WO 02/056790	7/25/02	PCT				
	B44	WO 03/000308	1/3/03	PCT				
	B45	WO 03/022323	3/20/03	PCT				
	B46	WO 03/028780	4/10/03	PCT				

<i>R</i>	B47	WO 03/037223	5/8/03	PCT				
<i>R</i>	B48	WO 03/039612	5/15/03	PCT				
<b>OTHER DOCUMENTS</b> (Including Author, Title, Date, Pertinent Pages, etc.)								
<i>DB</i>	C1	Anonymous, <i>Cardiologists Draw - Up The Dream Stent</i> , Clinica 710:15 (June 17, 1996), <a href="http://www.dialogweb.com/cgi/document?req=1061848202959">http://www.dialogweb.com/cgi/document?req=1061848202959</a> , printed 8/25/03 (2 pages).						
	C2	Anonymous, <i>Heparin-coated stents cut complications by 30%</i> , Clinica 732:17 (Nov. 18, 1996), <a href="http://www.dialogweb.com/cgi/document?req=1061847871753">http://www.dialogweb.com/cgi/document?req=1061847871753</a> , printed 8/25/03 (2 pages).						
	C3	Anonymous, <i>Rolling Therapeutic Agent Loading Device for Therapeutic Agent Delivery or Coated Stent</i> (Abstract 434009), Res. Disclos. pp. 974-975 (June 2000).						
	C4	Anonymous, <i>Stenting continues to dominate cardiology</i> , Clinica 720:22 (Sept. 2, 1996), <a href="http://www.dialogweb.com/cgi/document?req=1061848017752">http://www.dialogweb.com/cgi/document?req=1061848017752</a> , printed 8/25/03 (2 pages).						
	C5	Aoyagi et al., <i>Preparation of cross-linked aliphatic polyester and application to thermo-responsive material</i> , Journal of Controlled Release 32:87-96 (1994).						
	C6	Barath et al., <i>Low Dose of Antitumor Agents Prevents Smooth Muscle Cell Proliferation After Endothelial Injury</i> , JACC 13(2): 252A (Abstract) (Feb. 1989).						
	C7	Barbucci et al., <i>Coating of commercially available materials with a new heparinizable material</i> , J. Biomed. Mater. Res. 25:1259-1274 (Oct. 1991).						
	C8	Chung et al., <i>Inner core segment design for drug delivery control of thermo-responsive polymeric micelles</i> , Journal of Controlled Release 65:93-103 (2000).						
	C9	Dev et al., <i>Kinetics of Drug Delivery to the Arterial Wall Via Polyurethane-Coated Removable Nitinol Stent: Comparative Study of Two Drugs</i> , Catheterization and Cardiovascular Diagnosis 34:272-278 (1995).						
	C10	Dichek et al., <i>Seeding of Intravascular Stents with Genetically Engineered Endothelial Cells</i> , Circ. 80(5):1347-1353 (Nov. 1989).						
	C11	Eigler et al., <i>Local Arterial Wall Drug Delivery from a Polymer Coated Removable Metallic Stent: Kinetics, Distribution, and Bioactivity of Forskolin</i> , JACC, 4A (701-1), Abstract (Feb. 1994).						
	C12	Helmus, <i>Overview of Biomedical Materials</i> , MRS Bulletin, pp. 33-38 (Sept. 1991).						
	C13	Herdeg et al., <i>Antiproliferative Stent Coatings: Taxol and Related Compounds</i> , Semin. Intervent. Cardiol. 3:197-199 (1998).						
	C14	Inoue et al., <i>An AB block copolymer of oligo(methyl methacrylate) and poly(acrylic acid) for micellar delivery of hydrophobic drugs</i> , Journal of Controlled Release 51:221-229 (1998).						
	C15	Kataoka et al., <i>Block copolymer micelles as vehicles for drug delivery</i> , Journal of Controlled Release 24:119-132 (1993).						
	C16	Levy et al., <i>Strategies For Treating Arterial Restenosis Using Polymeric Controlled Release Implants</i> , Biotechnol. Bioact. Polym. [Proc. Am. Chem. Soc. Symp.], pp. 259-268 (1994).						
	C17	Liu et al., <i>Drug release characteristics of unimolecular polymeric micelles</i> , Journal of Controlled Release 68:167-174 (2000).						
	C18	Marconi et al., <i>Covalent bonding of heparin to a vinyl copolymer for biomedical applications</i> , Biomaterials 18(12):885-890 (1997).						
	C19	Matsumaru et al., <i>Embolic Materials For Endovascular Treatment of Cerebral Lesions</i> , J. Biomater. Sci. Polymer Edn 8(7):555-569 (1997).						
	C20	Miyazaki et al., <i>Antitumor Effect of Implanted Ethylene-Vinyl Alcohol Copolymer Matrices Containing Anticancer Agents on Ehrlich Ascites Carcinoma and P388 Leukemia in Mice</i> , Chem. Pharm. Bull. 33(6) 2490-2498 (1985).						
	C21	Miyazawa et al., <i>Effects of Pemirolast and Tranilast on Intimal Thickening After Arterial Injury in the Rat</i> , J. Cardiovasc. Pharmacol., pp. 157-162 (1997).						

R	C22	Nordrehaug et al., A novel biocompatible coating applied to coronary stents, European Heart Journal 14, p. 321 (P1694), Abstr. Suppl. (1993).
	C23	Ohsawa et al., Preventive Effects of an Antiallergic Drug, Pemirolast Potassium, on Restenosis After Percutaneous Transluminal Coronary Angioplasty, American Heart Journal 136(6):1081-1087 (Dec. 1998).
	C24	Ozaki et al., New Stent Technologies, Progress in Cardiovascular Diseases, Vol. XXXIX(2):129-140 (Sept./Oct. 1996).
	C25	Pechar et al., Poly(ethylene glycol) Multiblock Copolymer as a Carrier of Anti-Cancer Drug Doxorubicin, Bioconjugate Chemistry 11(2):131-139 (Mar./Apr. 2000).
	C26	Peng et al., Role of polymers in improving the results of stenting in coronary arteries, Biomaterials 17:685-694 (1996).
	C27	Shigeno, Prevention of Cerebrovascular Spasm By Bosentan, Novel Endothelin Receptor, Chemical Abstract 125:212307 (1996).
	C28	van Beusekom et al., Coronary stent coatings, Coronary Artery Disease 5(7):590-596 (July 1994).
	C29	Wilensky et al., Methods and Devices for Local Drug Delivery in Coronary and Peripheral Arteries, Trends Cardiovasc. Med. 3(5):163-170 (1993).
I	C30	Yokoyama et al., Characterization of physical entrapment and chemical conjugation of adriamycin in polymeric micelles and their design for in vivo delivery to a solid tumor, Journal of Controlled Release 50:79-92 (1998).
EXAMINER	DATE CONSIDERED 07/30/2004	
EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 809; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

<b>Notice of References Cited</b>	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,379,379	04-2002	Wang, Lixiao	623/1.15
	B	US-4,142,526	03-1979	Zaffaroni et al.	424/424
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Gene Michal	Examiner: Hieu Phan
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Commissioner for Patents  
USPTO  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Dear Examiner Phan:

This responds to the Office Action dated October 4, 2004.

Specification amendments begin at page 2.

Claim amendments begin at page 3.

Remarks begin at page 5.

**AMENDMENTS TO THE SPECIFICATION:**

Please replace the abstract with the following replacement abstract:

A coated stent is provided including a coating ~~comprising~~  
composed of one or more co-polymers of ethylene with  
carboxylic acid wherein the carboxylic acid co-monomer  
content is 5-50 wt%.

Please replace the section entitled Cross Reference with the following replacement section:

**Cross Reference**

This is a divisional of U.S. patent application serial number 09/748,719 filed December 22, 2000, which issued on November 30, 2004 as U. S. Patent No. 6,824,559.



**AMENDMENTS TO THE CLAIMS:**

Replacement Claim Set:

37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.
38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.
42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Previously presented) The drug delivery matrix of claim 37, additionally comprising an implantable substrate wherein the copolymer is a coating on the implantable substrate.
44. (Previously presented) A method of coating an implantable medical device, comprising:  
  
adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and  
allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

**REMARKS**

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 37-49 are pending.
- Claims 37-49 are rejected.

Applicant has amended the abstract as required by the Examiner.

Applicant has amended the Cross Reference section to indicate that the parent patent application has now issued as a patent.

These amendments are not new matter.

The Examiner has rejected Claims 37-49 under 35 U.S.C. § 103(a) as being unpatentable over Wang in view of Zaffaroni et al.

Applicant has thoroughly searched the disclosure of Zaffaroni et al. and cannot locate any place in Zaffaroni that teaches an ethylene-carboxylic acid copolymer. Nor can applicant find such a copolymer with 5-50 wt% of carboxylic acid monomer. Moreover, the only discussion directed at release rate in Zaffaroni appears to be directed at the ratio of acid hydrogen to esterified acidic hydrogen. Therefore, the cited combination does not teach every element of these claims. Furthermore, the Examiner has not provided facts supporting an advantage for combining the cited references; the Examiner has not indicated where that advantage is taught. Applicant do not know whether the Examiner is relying on some disclosure in Zaffaroni for this purported advantage or whether he is relying on the knowledge of one of ordinary skill in the art. If it is the former, Applicant asks that the Examiner point out where Zaffaroni teaches that advantage. If it the latter, the Examiner is taking official notice of the advantage. If so, Applicant traverses this act and asks for specific evidence that one of ordinary skill in the art would have recognized the advantage of combining the cited references. Applicant are entitled to make that request according MPEP §2144.03.

Furthermore, "in order to complete the PTO's prima facie case and shift the burden of going forward to applicant, there must be evidence (other than speculation by the PTO) that one of ordinary skill in the art would have been motivated to make the modification of the prior art necessary to arrive at the claimed subject matter." *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941, 1944 (Fed. Cir. 1992). Applicant asks for evidence to support the identified motivation.

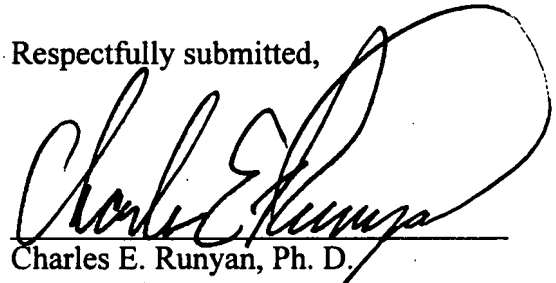
Since prima facie obviousness has not been made out, please remove this rejection.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Date: January 4, 2005

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0235  
crunyan@ssd.com

Respectfully submitted,

  
Charles E. Runyan, Ph. D.  
Attorney for Applicant  
Reg. No. 43,066

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

Date: 01/04/05 By: Patricia J. Smith  
Name of person signing certification



# UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,678

11/12/2003

Gene Michal

50623.352

9070

7590

03/22/2005

Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED *Response*  
*Due 6/22/05*  
MAR 25 2005  
BY *MP* CALENDARED *CB*  
ATTORNEY  
SQUIRE, SANDERS & DEMPSEY

# Office Action Summary

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Hieu Phan

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 37-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-49 is/are allowed.
- 6) ☒ Claim(s) 37-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3738

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 37-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Nyhart, Jr. (U.S. Patent 6,738,661).

Nyhart, Jr disclosed a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix as is claimed (column 7 lines 16-37).

***Response to Arguments***

3. Applicant's arguments, see paper 01/04/2005, filed 01/04/2005, with respect to claims 37-43 have been fully considered and are persuasive. The rejection of claim 37-43 in paper 10/04/2004 has been withdrawn.

***Allowable Subject Matter***

4. Claims 44-49 are allowed.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 571-272-4757. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan  
Examiner  
Art Unit 3738





<b>Notice of References Cited</b>	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,948,529	09-1999	Hastie, Allan J.	428/373
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,738,661 B1  
DATED : May 18, 2004  
INVENTOR(S) : Eldon H. Nyhart, Jr.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7.

Lines 59 and 63, please delete "C." and insert therefor -- C --.

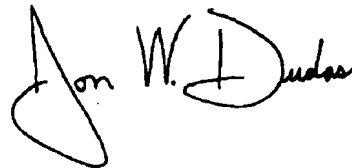
Column 12.

Line 30, please delete "describe" and insert thereof -- described --.

Line 61, please delete "and" and insert thereof -- an --.

Signed and Sealed this

Fourth Day of January, 2005

A handwritten signature in black ink, reading "Jon W. Dudas". The signature is stylized, with a large, looped initial "J" and a cursive "Dudas".

JON W. DUDAS  
*Director of the United States Patent and Trademark Office*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Gene Michal	Examiner: Hieu Phan
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Dear Examiner Phan:

This responds to the Office Action dated March 22, 2005.

Claim set begin at page 2; no claims are amended.

Remarks begin at page 4.

**AMENDMENTS TO THE CLAIMS:**

Replacement Claim Set:

37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.
38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.
42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Previously presented) The drug delivery matrix of claim 37, additionally comprising an implantable substrate wherein the copolymer is a coating on the implantable substrate.
44. (Previously presented) A method of coating an implantable medical device, comprising:  
  
adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and  
allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

**REMARKS**

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 37-49 are pending.
- Claims 37-43 are rejected.
- Claims 44-49 are allowed.

Applicant thanks the Examiner for the indication of allowable subject matter.

The Examiner has rejected Claims 37-43 under 35 U.S.C. § 102(e) as being anticipated by Nyhart (U.S. Patent No. 6,738,661)—D1.

Applicant has thoroughly searched the disclosure of D1 and cannot locate any place in D1 that teaches an ethylene-carboxylic acid copolymer. Therefore, Claim 37 does not teach or disclose every element of Claim 37. Claims 37 is patentable over D1.

Claims 38-43 depend from Claim 37 and contain all the limitations of Claim 37. This makes these dependent claims patentable over D1 for at least the same reasons that were discussed for the independent claims. Please remove the rejection of these claims, as well.

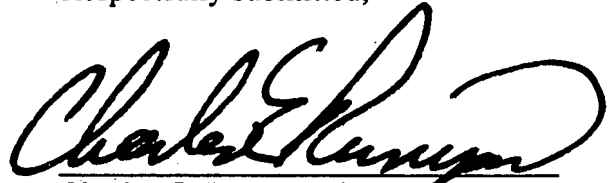
Furthermore, Applicant can not find an ethylene-carboxylic acid copolymer with 5-50 wt% of carboxylic acid monomer, which means Claims 38-40 are patentable over D1 for this additional reason. Nor can Applicant find such a copolymer wherein the carboxylic acid is selected from the list recited in Claim 42 or wherein the copolymer is the copolymer recited in Claim 41. Therefore, Claims 41 and 42 are patentable over D1 for this additional reason.

Claims 37-43 are patentable over D1 because D1 does not teach each element of these claims. Please remove this rejection.

If the Examiner contends that Applicant has missed the relevant disclosure, Applicant asks that the Examiner point out where in the reference the relevant disclosure exists and asks for a definition of acronyms, if any, that are used, but not defined, in the relevant disclosure.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



Charles E. Runyan, Ph. D.  
Attorney for Applicant  
Reg. No. 43,066

Date: June 22, 2005

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# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 06/29/2005

Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response  
Due 7/29/05

JUL 06 2005

BY MP CALENDARED CR  
ATTORNEY  
SQUIRE, SANDERS & DEMPSEY





UNITED STATES PATENT AND TRADEMARK OFFICE

10, 7/26/08

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
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ALEXANDRIA, VA 22313-1450  
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Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 6/22/08 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_
- ☐ 3. Amendments to the drawings: \_\_\_\_\_
- ☒ 4. Amendments to the claims:
- ☒ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
  - ☒ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☐ E. Other: \_\_\_\_\_

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION (including a submission for an RCE)**, and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. **The period for response to a final rejection continues to run from the date set in the final rejection**, and is not affected by the non-compliant status of the amendment.

*Sinda W. King*  
Legal Instruments Examiner (LIE)

571-272-4397  
Telephone No.

Express Mail No. EV 721 157 250 US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Gene Michal	Examiner: Hieu Phan
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Dear Examiner Phan:

This responds to the Notice of Non-Compliant Amendment dated June 29, 2005.

Claim set begin at page 2; no claims are amended.

Remarks begin at page 4.

**AMENDMENTS TO THE CLAIMS:**

Replacement Claim Set:

- 1-36. (Canceled).
37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.
38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.
42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Previously presented) The drug delivery matrix of claim 37, additionally comprising an implantable substrate wherein the copolymer is a coating on the implantable substrate.
44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

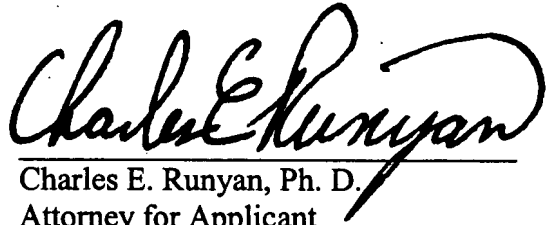
45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

**REMARKS**

Applicant re-submits the Amendments to the Claims Section. But also points out that Applicant amended no claims in the previous response and therefore Applicant provided the claim listing only as a convenience to the Examiner. Since Applicant made no amendment, the amendment was not non-compliant.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



Charles E. Runyan, Ph. D.  
Attorney for Applicant  
Reg. No. 43,066

Date: July 7, 2005

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Suite 300  
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San Francisco, CA 94111

EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED *Response*  
*Due 12/29/05*  
OCT 03 2005

BY *ED* CALENDARED  
ATTORNEY *BR*  
SQUIRE, SANDERS & DEMPSEY

**Office Action Summary**

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Hieu Phan

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-49 is/are allowed.
- 6) ☒ Claim(s) 37-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512).

Rhodes et al. disclosed a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix as is claimed (column 1 lines 41-68 and column 2 lines 1-6).

***Response to Arguments***

3. Applicant's arguments see paper 01/04/2005, filed 03/22/2005, with respect to claims 37-43 have been fully considered and are persuasive. The rejection of claim 37-43 in paper 03/22/2005 has been withdrawn.

***Allowable Subject Matter***

4. Claims 44-49 are allowed.



Art Unit: 3738

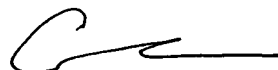
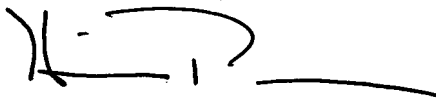
**Conclusion**

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 571-272-4757. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan  
Examiner  
Art Unit 3738



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY GROUP 1100

<b>Notice of References Cited</b>	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,401,512	03-1995	Rhodes et al.	424/458
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



US005401512A

**United States Patent** [19]

Rhodes et al.

[11] **Patent Number:** 5,401,512[45] **Date of Patent:** Mar. 28, 1995[54] **DELAYED RELEASE ORAL DOSAGE FORMS FOR TREATMENT OF INTESTINAL DISORDERS**

[76] **Inventors:** John Rhodes, 25 Nantfawr Road, Cyncoed, Cardiff, South Glamorgan CF2 6JO; Brian K. Evans, 9 Merevale, The Common, Dinas Powis, South Glamorgan CF6 4HS, both of United Kingdom

[21] **Appl. No.:** 107,744[22] **PCT Filed:** Feb. 21, 1992[86] **PCT No.:** PCT/GB92/00318

§ 371 Date: Aug. 20, 1993

§ 102(e) Date: Aug. 20, 1993

[87] **PCT Pub. No.:** WO92/14452**PCT Pub. Date:** Sep. 3, 1992[30] **Foreign Application Priority Data**

Feb. 22, 1991 [GB] United Kingdom ..... 9103795

[51] **Int. Cl.<sup>6</sup>** ..... A61K 9/58[52] **U.S. Cl.** ..... 424/458; 424/461; 424/462; 424/463[58] **Field of Search** ..... 424/458, 462, 463, 461[56] **References Cited****U.S. PATENT DOCUMENTS**

4,250,166 2/1981 Mackawa et al. .... 424/419

5,260,071 11/1993 Lemelson ..... 424/463

5,283,064 2/1994 Suzuki et al. .... 424/463

**FOREIGN PATENT DOCUMENTS**

0040590 11/1981 European Pat. Off. .

0080341 6/1983 European Pat. Off. .

0366621 5/1990 European Pat. Off. .

0375063 6/1990 European Pat. Off. .

0386967 9/1990 European Pat. Off. .

3034929 2/1991 Japan .

2021407 12/1979 United Kingdom .

WO81/02671 10/1981 WIPO .

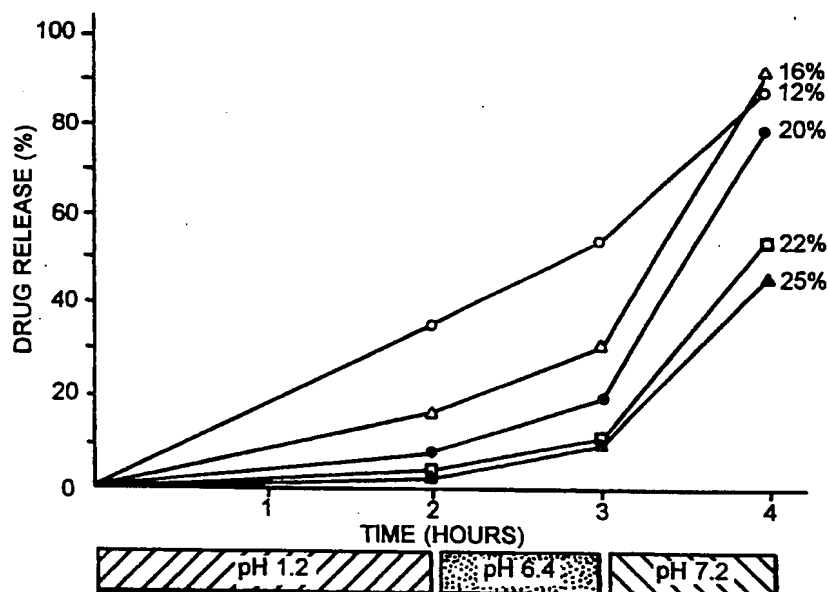
WO83/00435 2/1983 WIPO .

**OTHER PUBLICATIONS**

Roth et al 'hagers handbuch der pharmazeutischen praxis' 1971, Springer-verlag, Berlin Heidelberg New-York pp. 494-495, Nachbehandlungen von Gelatinkapseln.

*Primary Examiner*—Thurman K. Page*Assistant Examiner*—Amy Hulina*Attorney, Agent, or Firm*—Nixon & Vanderhye[57] **ABSTRACT**

An orally administrable pharmaceutical dosage form for selectively administering a drug to the intestine comprises a plurality of enteric coated granules of the drug contained in an enterically coated capsule which releases the granules in the small intestine. The granules are preferably coated with a coating which remains intact until the coated granules reach at least the ileum and thereafter provide a sustained release of the drug in the colon. Suitable coating materials are selected from the Eudragit range of (meth)acrylate and (meth)acrylic and polymers. The invention has particular application to topically active drugs such as topically active steroids, bismuth salts and complexes, and especially, 5-amino-salicylic acid.

**19 Claims, 1 Drawing Sheet**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  Gene Michal	Examiner:  Hieu Phan
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Dear Examiner Phan:

This is a response to the Office Action dated September 29, 2005, which has a shortened statutory period for reply that is set to expire on December 29, 2005.

Amendments to Claims begin at page 2.

Remarks begin at page 5.

**AMENDMENTS TO THE CLAIMS:**

- 1-36. (Canceled).
37. (Currently amended) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.
38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.
42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Canceled).
44. (Allowed) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Allowed) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Currently amended) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent ~~ee-~~ solvents.
47. (Allowed) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Allowed) The method of claim 44, wherein the solvent system comprises toluene.
49. (Allowed) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.
50. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
51. (New) The method of claim 50, wherein the carboxylic acid co-monomer content

is no more than 50% by weight.

- 52. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
- 53. (New) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.
- 54. (New) The method of claim 44, wherein the device comprises a stent.
- 55. (New) The drug delivery matrix of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

**REMARKS**

***Claim Rejections – 35 U.S.C. § 102***

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 50-55 are new.

Claims 44-49 have been allowed.

Claim 43 is now canceled.

Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), (“Rhodes”).

Amended, independent Claim 37 recites, “A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.”

Rhodes fails to teach or suggest that the “copolymer is a coating on an implantable substrate” as recited by amended, independent Claim 1 of the present invention. Rather, Rhodes provides “an orally administrable formulation for selectively administering the drug to the large intestine” (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and claims dependent thereon are in condition for allowance.




*Conclusion*

Claims 37-42 and 44-55 are pending in this application. Claims 37-42 have been placed in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: November 30, 2005

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Angie M. Augustus  
Attorney for Applicant  
Reg. No. 51,421



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10/712,678

11/12/2003

Gene Michal

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12/14/2005

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EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response due  
1/14/05  
DEC 19 2005  
BY ED CALENDARED  
ATTORNEY SQUIRE, SANDERS & DEMPSEY AMA



UNITED STATES PATENT AND TRADEMARK OFFICE

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THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
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  - ☐ B. New paragraph(s) should not be underlined.
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  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: THE WORD ALLOWED IS NOT THE PROPER STATUS IDENTIFIER

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION (including a submission for an RCE)**, and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

*Stefanie Bryce*  
Legal Instruments Examiner (LIE)  
STEFANIE BRYCE

571-272-4334  
Telephone No.



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 12/14/2005

Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

EXAMINER

PHAN, HIEU

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response due  
1/14/05

DEC 19 2005

BY ED CALENDARED  
ATTORNEY AMA  
SQUIRE, SANDERS & DEMPSEY

**Notice of Non-Compliant  
Amendment (37 CFR 1.121)**

10712678

Applicant(s)

Examiner

Art Unit

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 11/30/05 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: *"Allowed" is not proper status identifier.*
- ☐ 5. The amendment is unsigned or not signed in accordance with 37 CFR 1.4.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

**TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:**

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121 or 1.4, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

R. Johnson

571-272-4359

Legal Instruments Examiner (LIE)

Telephone No.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  Gene Michal	Examiner:  Hieu Phan
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE OF NON-COMPLAINT AMENDMENT**

Dear Examiner Phan:

This is a response to the Notice of Non-Complaint Amendment dated December 14, 2005, which has a shortened statutory period for reply that is set to expire on January 14, 2006.

Amendments to the Claims begin at page 2.

Remarks begin at page 5.

**AMENDMENTS TO THE CLAIMS:**

- 1-36. (Canceled).
37. (Currently amended) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.
38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.
42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Canceled).
44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Currently amended) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent ~~ee-~~ solvents.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.
50. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
51. (New) The method of claim 50, wherein the carboxylic acid co-monomer content



is no more than 50% by weight.

52. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
53. (New) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.
54. (New) The method of claim 44, wherein the device comprises a stent.
55. (New) The drug delivery matrix of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

**REMARKS**

***Claim Rejections – 35 U.S.C. § 102***

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 50-55 are new.

Claims 44-49 have been allowed.

Claim 43 is now canceled.

Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), (“Rhodes”).

Amended, independent Claim 37 recites, “A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.”

Rhodes fails to teach or suggest that the “copolymer is a coating on an implantable substrate” as recited by amended, independent Claim 1 of the present invention. Rather, Rhodes provides “an orally administrable formulation for selectively administering the drug to the large intestine” (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and claims dependent thereon are in condition for allowance.

***Conclusion***

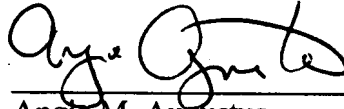
Claims 37-42 and 44-55 are pending in this application. Claims 37-42 have been placed in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: January 6, 2006

---

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0200



---

Angie M. Augustus  
Attorney for Applicant  
Reg. No. 51,421



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/712,678

11/12/2003

Gene Michal

50623.352

9070

7590

03/22/2006

DOCKETED:

FINAL OFFICE ACTION

due 6/22/06

Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

MAR 27 2006

BY:

TJB

Attv: AMA

SQUIRE, SANDERS & DEMPSEY

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/712,678	Applicant(s) MICHAL, GENE	
	Examiner Alvin J. Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-42 and 44-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-54 is/are allowed.
- 6) ☒ Claim(s) 37-42 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-42 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al US Patent 5,401,512.

Rhodes et al discloses a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix (see col. 1, lines 41-68 and col. 2, lines 1-6).

***Response to Arguments***

Applicant's arguments filed January 06, 2006 have been fully considered but they are not persuasive. The Examiner noticed the new limitations entered in claim 37. However, the Examiner has not given patentable weight to the "wherein" clause because a "wherein" clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. *See Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1010 (Fed. Cir. 1993); *Griffin v. Bertina*, 62 USPQ2d 1431 (Fed. Cir. 2002); *Amazon.com Inc. v. Barnesandnoble.com Inc.*, 57 USPQ2d 1747 (Fed. Cir. 2001).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 3738

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**

March 20, 2006.



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  Gene Michal	Examiner:  Alvin J. Stewart
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO OFFICE ACTION**

Dear Examiner Stewart:

This is a response to the Final Office Action dated March 22, 2006, which has a shortened statutory period for reply that is set to expire on June 22, 2006.

Amendments to the Specification begin at page 2.

Amendments to the Claims begin at page 3.

Remarks begin at page 6.

**AMENDMENTS TO THE SPECIFICATION**

Please amend page 13, lines 8-12 as follows:

A polycarbonate-urethane material such as Bionate 80 is very hygroscopic. Pellets of Bionate 80 are dried by a process, such as with a forced air dehumidifying dryer at 82 degrees C, ~~For~~ C for at least about 4 hours prior to extrusion or injection molding. Bionate 80 pellets are typically filtered during extrusion, ~~though~~ through filters such as a 350 mesh filter and two 500 mesh filters.

**AMENDMENTS TO THE CLAIMS:**

- 1-36. (Canceled).
37. (Currently amended) A drug delivery ~~matrix~~, coating on an implantable medical device, the coating comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the coating matrix, ~~wherein the copolymer is a coating on an implantable substrate.~~
38. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
39. (Currently amended) The drug delivery ~~matrix~~ coating of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
40. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
41. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the co-polymer is ethylene acrylic acid.
42. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
43. (Canceled).
44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.
50. (Previously presented) The method of claim 44, wherein the carboxylic acid comonomer content is no less than 5% by weight.
51. (Previously presented) The method of claim 50, wherein the carboxylic acid comonomer content is no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.
54. (Previously presented) The method of claim 44, wherein the device comprises a stent.
55. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

**REMARKS**

***Claim Rejections – 35 U.S.C. § 102***

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 37-42, 55 are currently amended.

Claims 44-54 have been allowed.

Claim 43 has been canceled.

Claims 37-43 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), (“Rhodes”).

The Examiner has not given patentable weight to the “wherein” clause, “because a ‘wherein’ clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim” (Office Action, Page 2).

In response, Applicants have amended Claim 37 to clarify that an implantable device is patentably or substantively part of Claim 37. Please reconsider arguments presented below in light of this amendment.

Amended Claim 37 now recites, “**A drug delivery coating on an implantable substrate...**”

Rhodes fails to teach or suggest that the “**A drug delivery coating on an implantable substrate...**” as recited by Amended Claim 37. Rather, Rhodes discloses “an orally administrable formulation for selectively administering the drug to the large intestine” (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and dependent Claims 38-42 and 55, are in condition for allowance.

**CONCLUSION**

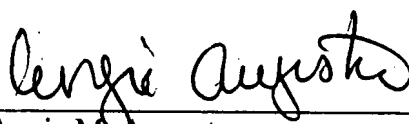
Claims 37-42 and 44-55 are pending in this application. Claims 44-54 have been allowed. Claims 37-42 and 55 are now in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: May 8, 2006

---

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0200

  
\_\_\_\_\_  
Angie M. Augustus  
Attorney for Applicant  
Reg. No. 51,421



# UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 05/25/2006

Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

DOCKETED: see below

EXAMINER

STEWART, ALVIN J

ART UNIT PAPER NUMBER

3738

MAY 31 2006

DATE MAILED: 05/25/2006

BY: TJB Attv: AMA  
SQUIRE, SANDERS & DEMPSEY

Please find below and/or attached an Office communication concerning this application or proceeding.

ADVISORY ACTION - due 6/22/06  
w/ 1 mo. extension - 7/22/06  
w/ 2 mo. extension - 8/22/06  
DROP DEAD DATE - 9/22/06



**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Alvin J. Stewart

Art Unit

3738

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 08 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE:

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 44-54.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 37-42 and 55.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit: 3738

Continuation of 3. NOTE: The new limitations are positively claiming a coating. For the above reasons, the new limitations required a further consideration.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  Gene Michal	Examiner:  Alvin J. Stewart
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL RESPONSE TO OFFICE ACTION**

Dear Examiner Stewart:

This is a supplemental response to the Final Office Action dated March 22, 2006, which has a shortened statutory period for reply that is set to expire on June 22, 2006. Since the last response to the final office action was not entered, Applicants believes that they have used the correct claim identifiers and are resubmitting the amendment to the specification.

**AMENDMENTS TO THE SPECIFICATION**

Please amend page 13, lines 8-12 as follows:

A polycarbonate-urethane material such as Bionate 80 is very hygroscopic. Pellets of Bionate 80 are dried by a process, such as with a forced air dehumidifying dryer at 82 degrees C, ~~For~~ C for at least about 4 hours prior to extrusion or injection molding. Bionate 80 pellets are typically filtered during extrusion, ~~though~~ through filters such as a 350 mesh filter and two 500 mesh filters.

**AMENDMENTS TO THE CLAIMS:**

- 1-43. (Canceled).
44. (Previously presented) A method of coating an implantable medical device, comprising:
- adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;
  - applying the composition to an implantable medical device; and
  - allowing the solvent system to evaporate.
45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.
51. (Previously presented) The method of claim 50, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.
53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.
54. (Previously presented) The method of claim 44, wherein the device comprises a stent.
55. (Canceled)

**REMARKS**

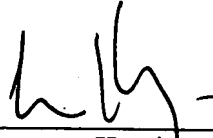
Claims 44-54 have been allowed. Claims 37-42 and 55 are canceled by this response. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: June 2, 2006

---

Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0200

  
\_\_\_\_\_  
Cameron Kerrigan  
Attorney for Applicant  
Reg. No. 44,826



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 08/24/2006

Cameron K. Kerrigan

Squire, Sanders & Dempsey L.L.P.

Suite 300

1 Maritime Plaza

San Francisco, CA 94111

DOCKETED: due 11/24/06

**AUG 29 2006**

BY: fib Attv: AMA  
SQUIRE, SANDERS & DEMPSEY

EXAMINER

STEWART, ALVIN J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



# Office Action Summary

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Alvin J. Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 44-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Response to Amendment***

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-52 recite the limitation "carboxylic acid comonomer" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al US Patent 5,631,328.

Wang et al discloses a method of making a coat having the step of adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition (see col. 2, lines 52-60); applying the composition to an implantable medical device (see col. 17, lines 38-42) and allowing the solvent system to evaporate (see col. 8, lines 62-65).

Regarding claim 45, see col. 3, lines 43 and 54.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Chabreck et al US Patent 6,087,412.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a solvent system made of toluene.

Chabreck et al discloses a solvent made of toluene for the purpose of having an inert solvent (see col. 9, lines 65-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the solvent of the Wang et al reference with the toluene solvent of the Chabreck et al reference in order to have an inert solvent.

Regarding claims 50-52, disclose the claimed invention except for having a carboxylic acid comonomer between 5 to 50 percent by weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the percentage by weight of the copolymer, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA.1980).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Kliment et al US Patent 4,729,914.

Art Unit: 3738

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a chlorinated solvent.

Kliment et al teaches a copolymer having a solvent and the solvent is chlorinate for the purpose of obtaining an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures (see col. 4, lines 4-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Wang et al reference with the Kliment reference in order to obtain an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

August 7, 2006.

**Notice of References Cited**

Application/Control No.

10/712,678

Applicant(s)/Patent Under  
Reexamination  
MICHAL, GENE

Examiner

Alvin J. Stewart

Art Unit

3738

Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,729,914	03-1988	Kliment et al.	428/35.7
*	B	US-5,631,328	05-1997	Wang et al.	525/329.7
*	C	US-6,087,412	07-2000	Chabreck et al.	522/35
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**CERTIFICATE OF CORRECTION**

**PATENT NO. :** 4,729,914

**DATED :** March 8, 1988

**INVENTOR(S) :** Charles K. Kliment and George E. Seems

It is certified that error appears in the above—identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6, line 34 delete "1" and insert --2--.

**Signed and Sealed this**  
**Ninth Day of August, 1988**

*Attest:*

**DONALD J. QUIGG**

*Attesting Officer*

*Commissioner of Patents and Trademarks*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  Gene Michal	Examiner:  Alvin J. Stewart
Serial No. 10/712,678	Art Unit: 3738
Filed: November 12, 2003	
Title: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDMENT AND RESPONSE TO OFFICE ACTION**

Dear Examiner Stewart:

This is a response to the Office Action mailed on August 24, 2006.



**IN THE CLAIMS**

- 1-43. (Canceled).
44. (Currently amended) A method of coating an implantable medical device, comprising:
- adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;
- applying the composition to an implantable medical device; and
- allowing the solvent system to evaporate.
45. (Currently amended) The method of claim 44, wherein the carboxylic acid comonomer is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.
46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.
47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.
48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.
49. (Previously presented) The method of claim 48, wherein the solvent system fur-

ther comprises a chlorinated solvent and a lower alcohol.

50. (Currently amended) The method of claim 44, wherein the carboxylic acid comonomer has a content in the copolymer ~~is~~ no less than 5% by weight.
51. (Currently amended) The method of claim 50, wherein the carboxylic acid comonomer has a content in the copolymer ~~is~~ no more than 50% by weight.
52. (Currently amended) The method of claim 44, wherein the carboxylic acid comonomer has a content in the copolymer ~~is~~ no more than 50% by weight.
53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.
54. (Previously presented) The method of claim 44, wherein the device comprises a stent.
55. (Canceled)

**REMARKS**

Claims 44-54 are pending. Claims 44-54 are rejected. For record, claims 44-54 were previously allowed. Claims 37-42 and 55 were canceled.

**Rejections under 35 U.S.C. §112, second paragraph**

Claims 50-52 have been rejected as being indefinite under 35 U.S.C. §112, second paragraph, for allegedly failing to provide an antecedent basis for "carboxylic acid comonomer." Applicants believe the amendment in this response cures the rejections.

**Rejections under 35 U.S.C. §102**

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang").

Claim 44 defines a method of coating an implantable medical device. The method comprising (1) adding a copolymer of an ethylene comonomer with **a carboxylic acid comonomer** to a solvent system to form a composition, (2) applying the composition to an implantable medical device, and (3) allowing the solvent system to evaporate.

Wang describes forming a composition of ionomers that can form a film (col. 6, lines 17-63). The composition can be formed of three monomers: (a) an alpha-olefin, (b) **an ester** of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) **a metal salt** of acrylic or methacrylic acid (col. 4, line 59 through col. 5, line 63). **Wang does not describe forming a coating including a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Esters of a carboxylic acid and metal salts of a carbox-**

lylic acid are totally different chemical entities from the carboxylic acid. In addition, esters of a carboxylic acid and metal salts of a carboxylic acid have totally different physical and mechanical properties than the carboxylic acid. For example, as an ordinary artisan would recognize, an ester of a carboxylic acid is more hydrophobic than the carboxylic acid. Conversely, a metal salt of the carboxylic acid is more hydrophilic than the carboxylic acid. A film formed of an ester of a carboxylic acid or a metal salt of a carboxylic acid would have totally different physical, mechanical, or drug release properties than a film formed of a carboxylic acid. A key aspect of the Wang reference is to use a combination of an ester and metal salt of a carboxylic acid monomers for forming a film which has low haze (col. 1, lines 13-19), which attests to the different film properties that different monomers in a polymer of the film can impart to the film.

Accordingly, claim 44 is patentably allowable over Wang. Claims 45, 46, 53 and 54 depend from claim 44 and are patentably allowable over Wang for at least the same reason.

#### Rejections under 35 U.S.C. §103

Claims 47, 48, and 50-52 are rejected under 35 U.S.C. 103(a) as being obvious over Wang in view of U.S. Patent No. 6,087,412 to Chabreck et al. ("Chabreck").

Claims 47, 48 and 50-52 depend from claim 44, which is discussed above, and therefore require a copolymer of an ethylene comonomer with a carboxylic acid comonomer.

Chabreck describes a macromer that include a segmented copolymer which is an

amide (col. 1, line 20 through col. 2, line 23). Chabreck does not **describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer**. Therefore, Chabreck does not cure the deficiencies of Wang, which is discussed above. Therefore, claims 47, 48 and 50-52 are patentably allowable over Wang in view of Chabreck.

Claim 49 is rejected as being obvious over Wang in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment").

Claim 49 depends from claim 44, which is discussed above, and therefore requires **a copolymer of an ethylene comonomer with a carboxylic acid comonomer**.

Kliment describes forming an N-vinylpyrrolidone copolymer that can include ethylenic monomers such as hydroxylethyl methacrylate or hydroxylpropyl acrylate. **Hydroxylethyl methacrylate or hydroxylpropyl acrylate is an ester of methacrylate or acrylate, which is not a carboxylic acid monomer** (see the discussion of Wang, *supra*). Therefore, Kliment does not describe **a copolymer of an ethylene comonomer with a carboxylic acid comonomer** and thus does not cure the deficiency of Wang. Accordingly, claim 49 is patentably allowable over Wang in view of Kliment.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

**CONCLUSIONS**

Withdrawal of the rejection and allowance of the claims are respectfully requested.

**If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the under-**


**signed attorney for approval of an Examiner's amendment.** If the Examiner has any

questions or concerns, the Examiner is invited to telephone the undersigned attorney at

(415) 393-9885.

Date: November 7, 2006  
Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111  
Telephone (415) 393-9885  
Facsimile (415) 393-9887

Respectfully submitted,

  
\_\_\_\_\_  
Zhaoyang Li, Ph.D.  
Reg. No. 46,872



## UNITED STATES PATENT AND TRADEMARK OFFICE

2398D

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	DOCKETED: Gene Michal	50623.352	9070
7590 Cameron K. Kerrigan Squire, Sanders & Dempsey L.L.P. Suite 300 1 Maritime Plaza San Francisco, CA 94111		02/12/2007 <b>FINAL REJECTION</b> <b>FEB 15 2007</b> BY: <u>tyb</u> Atty: <u>PL</u> SQUIRE, SANDERS & DEMPSEY		
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE		DELIVERY MODE
3 MONTHS		02/12/2007		PAPER

EXAMINER	
STEWART, ALVIN J	
ART UNIT	PAPER NUMBER
3738	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**FINAL OFFICE ACTION**  
RESPONSE DUE: 5/12/07  
NTC of APPEAL DUE: 8/12/07

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/712,678		MICHAL, GENE	
	<b>Examiner</b>		<b>Art Unit</b>	
	Alvin J. Stewart		3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 0706.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |



***Response to Arguments***

Applicant's arguments filed 11/07/07 have been fully considered but they are not persuasive.

The meaning of the word comonomer is the following: one of the compounds that constitute a copolymer. Therefore, the Examiner believes that the reference still reads on the claims because the two compounds mentioned in the claim are part of a copolymer.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the word carboxylic acid comonomer is not disclosed in the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The word ethylene comonomer is not disclosed in the specification. Correction is required.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al US Patent 5,631,328.

Wang et al discloses a method of making a coat having the step of adding a copolymer of comonomer ethylene with a carboxylic acid comonomer to a solvent system to form a composition (see col. 2, lines 52-60); applying the composition to an implantable medical device (see col. 17, lines 38-42) and allowing the solvent system to evaporate (see col. 8, lines 62-65). The meaning of the word comonomer is the following: one of the compounds that constitute a copolymer. Therefore, the Examiner believes that the reference still reads on the claims because the two compounds mentioned in the claim are part of a copolymer.

Regarding claim 45, see col. 3, lines 43 and 54.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Chabreck et al US Patent 6,087,412.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a solvent system made of toluene.

Chabreck et al discloses a solvent made of toluene for the purpose of having an inert solvent (see col. 9, lines 65-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the solvent of the Wang et al reference with the toluene solvent of the Chabreck et al reference in order to have an inert solvent.

Regarding claims 50-52, disclose the claimed invention except for having a carboxylic acid comonomer between 5 to 50 percent by weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the percentage by weight of the copolymer, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Kliment et al US Patent 4,729,914.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a chlorinated solvent.

Kliment et al teaches a copolymer having a solvent and the solvent is chlorinate for the purpose of obtaining an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures (see col. 4, lines 4-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Wang et al reference with the Kliment reference in order to

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obtain an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*  
ALVIN J. STEWART  
PRIMARY EXAMINER  
Art Unit 3738

February 02, 2007.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 04/11/2007  
Cameron K. Kerrigan  
Squire, Sanders & Dempsey L.L.P.  
Suite 300  
1 Maritime Plaza  
San Francisco, CA 94111

**ADVISORY ACTION**  
RESPONSE DUE: 5/12/07  
w/ 1 MONTH EXT: 6/12/07  
w/ 2 MONTH EXT: 7/12/07  
DROP DEAD DATE: 8/12/07

EXAMINER STEWART, ALVIN J	
ART UNIT 3738	PAPER NUMBER
MAIL DATE 04/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED: \_\_\_\_\_  
\_\_\_\_\_

APR 17 2007

BY: jb Altv: ZL  
SQUIRE, SANDERS & DEMPSEY

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/712,678

Applicant(s)

MICHAL, GENE

Examiner

Alvin J. Stewart

Art Unit

3738

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

*A. Stewart*  
ALVIN J. STEWART  
PRIMARY EXAMINER  
Art Unit: 3738

Continuation of 11. does NOT place the application in condition for allowance because: The Examiner stil believes that the previous rejection is proper. No new limitations have been entered.



# **RELATED PROCEEDINGS**

## **APPENDIX**

There are no related proceedings.